K011464

JUN 1 3 2001

510(k) SUMMARY

The 510(k) Summary is submitted in accordance with 21 CFR Part 807, Section 807.92

Submitter's Name: Guidant Corporation
Vascular Intervention

Submitter's Address: 26531 Ynez Road
Temecula, CA 92591

Telephone: (909) 914-4581
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Contact Person: Jennifer Pae Riggs

Date Prepared: May 11, 2001

Device Trade Name: RX VIATRAC™ 14
OTW VIATRAC™ 18
RX HERCULINK™ 14
RX HERCULINK™ PLUS
RX & OTW MEGALINK™ SDS

Device Common Name: Peripheral Dilatation Catheter
Biliary Stent System

Device Classification Name: Peripheral Transluminal Angioplasty Catheter
Biliary Catheter

Device Classification: Class II

Summary of Substantial Equivalence:

The design, materials, method of delivery and intended use features of the RX VIATRAC™ 14 and OTW VIATRAC™ 18 Peripheral Dilatation Catheters, RX HERCULINK™ 14, RX HERCULINK™ PLUS, and RX & OTW MEGALINK™ SDS Biliary Stent Systems are substantially equivalent with regard to these features in their predicate devices, RX VIATRAC™ 14 Peripheral Dilatation Catheter, OTW VIATRAC™ 18 Peripheral Dilatation Catheter, RX HERCULINK™ 14 Biliary Stent

System, RX HERCULINK™ PLUS Biliary Stent System, and the RX & OTW MEGALINK™ SDS Biliary Stent System.

Device Description:

There are no changes to the design. The only change is the new white foil marker material.

Intended Use:

There are no changes to the intended use.

Technological Characteristics:

Comparisons of the proposed and predicate devices show that the technological characteristics such as materials, performance characteristics, sterilization and packaging are identical or substantially equivalent to the currently marketed predicate devices. The only change is the new white foil marker material.

Performance Data:

The results of the verification testing demonstrate that the white foil marker material meets the established acceptance criteria and performs in a manner equivalent to the predicate device. No new safety or effectiveness issues were raised during the testing program.

Conclusions:

The RX VIATRAC™ 14 and OTW VIATRAC™ 18 Peripheral Dilatation Catheters, RX HERCULINK™ 14, HERCULINK™ PLUS, and the RX & OTW MEGALINK™ SDS Biliary Stent Systems have the same intended use, technological characteristics, performance properties, identical sterilization, and substantially equivalent materials. Therefore, there are no new safety or effectiveness issues. The The RX VIATRAC™ 14 and OTW VIATRAC™ 18 Peripheral Dilatation Catheters, RX HERCULINK™ 14, HERCULINK™ PLUS, and the RX & OTW MEGALINK™ SDS Biliary Stent Systems are substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 13 2001

Ms Jennifer Pae Riggs, RAC
Sr Regulatory Affairs Coordinator
Guidant Corporation
26531 Ynez Road
Temecula, CA 92591-4628

Re: K011464
Trade Name: RX VIATRAC™ 14 Peripheral Dilation Catheter
OTW VIATRAC™ 18 Peripheral Dialation Catheter
RX HERCULINK™ 14 Biliary Stent System
RX HERCULINK™ PLUS Biliary Stent System
RX & OTW MEGALINK™ SDS Biliary Stent System
Regulation Number: 870.1250, 876.5010
Regulation Class: II (two)
Product Code: DQY, LIT, FGE
Dated: May 11, 2001
Received: May 14, 2001

Dear Ms Riggs:

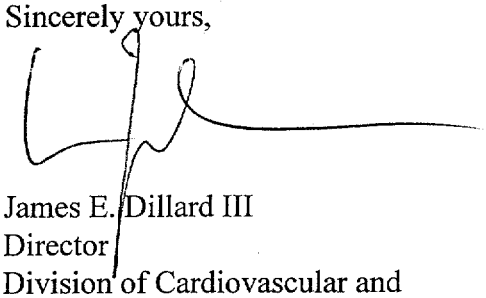
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish

further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.
This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,



James E. Dillard III
Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Indications for Use Statement

510(k) Number (if known) K011464

Device Name RX VIATRAC™ 14 Peripheral Dilatation Catheter

Indications for Use

The RX VIATRAC™ 14 Peripheral Dilatation Catheter is indicated:

- To dilate stenosis in the peripheral vasculature (iliac, femoral, ilio-femoral, popliteal, infra-popliteal and renal arteries) and for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae.
- For post-stent dilatation of the PALMAX™ P204 stent with the 20 mm balloon only, implanted in vessels 4.0 mm to 7.0 mm in diameter.

It is not intended for use in the coronary vasculature.

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____ OR Over-The-Counter Use_____
(Per 21 CFR 801.109)

Division of Cardiovascular & Respiratory Devices
510(k) Number K011464

Indications for Use Statement

510(k) Number (if known)

Device Name OTW VIATRAC™ 18 Peripheral Dilatation Catheter

Indications for Use

The OTW VIATRAC™ 18 Peripheral Dilatation Catheter is indicated:

- To dilate stenoses in the peripheral arteries (iliac, femoral, ilio-femoral, popliteal, infra-popliteal and renal arteries)
- For the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae.
- For post deployment optimization of the 28 mm and 38 mm MEGALINK™ Biliary Stent (6.0 to 10.0 mm diameters) and 18 mm MEGALINK™ Biliary Stent (6.0 to 8.0 mm diameters).

The OTW VIATRAC™ 18 Peripheral Dilatation Catheter is not intended for use in the coronary vasculature.

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____ OR Over-The-Counter Use_____
(Per 21 CFR 801.109)

Indications for Use Statement

510(k) Number (if known)

Device Name

RX HERCULINK™ 14 Biliary Stent System
RX HERCULINK™ PLUS Biliary Stent System
RX & OTW MEGALINK™ SDS Biliary Stent Systems

Indications for Use

The RX HERCULINK™ 14, RX HERCULINK™ PLUS, and the RX & OTW MEGALINK™ SDS Biliary Stent Systems are indicated:

- For the palliation of malignant strictures in the biliary tree.

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____ OR Over-The-Counter Use_____
(Per 21 CFR 801.109)